MPPC 20110

M.Pharmacy Degree Examinations - September, 2015

II Semester - Pharmaceutics

Paper- I: Advances in Drug Delivery Systems

(Regulation 2010-11)

Time : 3 Hours Maximum Marks: 70

Answer all the questions. All questions carry equal marks.

1. Explain the term 'sustained release'. How partition coefficient and stability of a drug are influencing in the design of a sustain release dosage form? Add note on polymer classification.

   (OR)

   Write the advantages and disadvantages of sustained release dosage forms. List the various biological factors affecting the performance of sustained release dosage forms and explain one factor in detail with an example.

2. Write the design and fabrication of oral controlled drug delivery systems.

   (OR)

   Write the design, evaluation and applications of any one implantable therapeutic system.

3. Write the design and evaluation of ocular drug delivery system.

   (OR)

   Discuss in detail about the factors to be considered and limitations in the design of protein and peptide drug delivery systems.

4. List the various methods used for the preparation of microspheres and describe any one method in detail. Add note on nano particles.

   (OR)

   Explain in detail about the production of monoclonal antibodies and write their applications.

5. Give an account on limitations and problems in delivery of drug to the brain and targeting to brain.

   (OR)

   Give an account on respiratory drug delivery system.

MPAN 20112

M.Pharmacy Degree Examinations - September, 2015

II Semester - Pharmaceutical Analysis

Paper- I: Spectroscopic Methods of Analysis

(Regulation 2012-13)

Time : 3 Hours Maximum Marks: 70

Answer all Questions. Each question carries Equal marks.

1. Explain the principle involved in the preparation of PDAB & FC reagents and explain their analytical applications in pharmaceutical practice.

(Or)

Explain the principle involved in UV Spectroscopy based on Beers's Lambert's law and derive its mathematical equation. Give a brief account on its instrumentation. Add a note on Woodward fisher's rule.

2. Write in detail the factors effecting the vibration of a molecule and explain the sample handling techniques in IR? Note on interpretation of IR Spectra.

(Or)

Explain the principle, theory, instrumentation and applications of Raman Spectroscopy.

3. Give a detailed note on spin — spin coupling and decoupling in NMR. Give an account on its application in structural elucidation

(Or)

Make a detailed note on (7 + 7)
(a) FT-NMR (b) CNMR

4. Explain the principle, theory, instrumentation and applications of mass spectroscopy.

(Or)

Write about (7+7)
(a) Chemical Ionization mass spectrometry
(b) Fast atom bombardment mass spectrometry

5. Write the principle, theory, instrumentation and applications of atomic absorption spectroscopy

(Or)

Explain the theory, principle and procedure involved in determination of (7+7)
(a) Potassium (b) Iodine

MPAN 20212

M.Pharmacy Degree Examinations - September, 2015

II Semester - Pharmaceutical Analysis

Paper- II: Advanced Analytical Techniques

(Regulation 2012-13)

Time : 3 Hours Maximum Marks: 70

Answer all Questions. All questions carry equal marks

1. Give the principle in X-Ray diffraction spectroscopy? Briefly explain the units of an X-Ray diffractometer? Write about applications and advantages of this technique.

   (Or)

   Write about production of X-Rays? Add a note on X-Ray absorption and X-Ray fluorescence with suitable examples.

2. Write short notes on (7+7)
   (a) TGA
   (b) DTA

   (Or)

   Explain the principle, theory, instrumentation and applications of DSC technique.

3. Explain the principle, theory and instrumentation in fluorimetry with a neat schematic diagram? Differentiate between fluorescence and phosphorescence.
   (Or)
   Explain different factors effecting fluorescence intensity? Make a special note on quenching and its types. Give pharmaceutical applications of fluorimetry.

4. Explain the theory and principle in Optical Rotatory Dispersion and with a neat diagram, explain working of a polarimeter

   (Or)

   Write in detail about (7+7)
   (a) Circular dichroism
   (b) Octane rule

5. Give the principle in RIA. Explain the methodology and applications of RIA in pharmaceutical analysis.

   (Or)

   Explain the principle in ICP? Give a detailed note on its instrumentation mechanism of working and applications.

MPAN 20312

M.Pharmacy Degree Examinations - September, 2015

II Semester - Pharmaceutical Analysis

Paper- III: Quality Assurance and Quality Control

(Regulation 2012-13)

Time : 3 Hours Maximum Marks: 70

Answer all Questions. Each question carries equal marks

1. What are the basic principles of quality control and explain the quality control tests carried out for evaluation of tablet dosage forms.

   (Or)

   Make a detailed note on quality control tests carried out for liquid orals as per I.P.

2. Explain in detail the concepts of GMP as per schedule M

   (Or)

   Describe the principles and objectives of (7+7)
   (a) TQM (b) ICH

3. (a) Write down the procedure for procurement of raw material. (7+7)
   (b) Make a note on selection of vendors and control of stores and stock

   (Or)

   Explain in brief (5+5+4)
   (a) Documents and records
   (b) SOP's
   (c) Master formula records

4. (a) Discuss the quality control tests for glass and plastic material. (8+6)
   (b) Make a note on quality control of labels and other printed material.

   (Or)

   (a) Note on maintenance of warehouse as per GMP specifications. (7+7)
   (b) Give the official standards for testing of rubber and metal containers.

5. Write a brief note on (7+7)
   (a) Waste and scrap disposal
   (b) Handling of returned goods

   (Or)

   Explain the procedure for evaluation of complaints and their recall procedures.

MPAN 20412

M.Pharmacy Degree Examinations - September, 2015

II Semester - Pharmaceutical Analysis

Paper- IV: Validation and Documentation

(Regulation 2012-13)

Time : 3 Hours | Maximum Marks: 70

Answer all Questions. Each question carries equal marks

1. Give a brief account on validation of the following: (7+7)
   (i) Equipment (ii) Cleaning

   (Or)

   Make a note on validation of the following: (7+7)
   (i) Methods and equipment for dry heat sterilization
   (ii) Processing techniques of mixing and granulation.

2. Give a detailed account on validation of analytical method as per ICH guidelines. Add a note on validation of dissolution test apparatus.

   (Or)

   Describe the validation procedures for the following instruments. (7+7)
   (i) HPLC (ii) UV — Visible spectrophotometer

3. What are different methods and equipments adopted for data storage?

   (Or)

   What is data generation plan? Explain its basic principle and significance in pharmaceutical R & D. List out the steps involved in development of data generation plan.

4. Make a detailed note on (7+7)
   (i) Quality review for finished products
   (ii) Describe the principles and objectives of Total Quality Management.

   (Or)

   (iii) Explain in brief quality review and quality audit.
   (iv) Add a note on batch release and its documentation.

5. Explain the procedure for validation of building and manufacturing premises for tablet preparation as per contract manufacturing.

   (Or)

   What is contract manufacturing? Explain in detail highlighting its advantages.

MPPC 20112

M.Pharmacy Degree Examinations - September, 2015

II Semester - Pharmaceutics

Paper- I: Advances in Drug Delivery Systems-I

(Regulation 2012-13)

Time : 3 Hours Maximum Marks: 70

Answer all the questions. All questions carry the equal marks.

1. Explain about the factors influencing design and performance of controlled release products?

(OR)

2. Write the classification of polymers? Explain the special advantages of biodegradable and natural polymers with suitable examples?

3. Write the classification of parental controlled release drug delivery systems? Explain in detail about the a) Solutions b) Coarse dispersions c) Micro-particles

(OR)

4. Define Transdermal systems (TDS)? What are their advantages, limitations and classify them. Discuss in detail about the preparation of rate- programmed systems?

5. a) What is the advantage of bucco-adhesive systems? Which types of polymers are used in it? Explain about their ideal characteristics? (7)
   b) Write about the mechanism of bio-adhesion? (7)

(OR)

6. a) Write about the preparation & polymers used in ocular drug systems? (7)
   b) Write a short note on Intra-uterine drug systems? (7)

7. Define liposomes and classify them? Explain about the methods for preparation of liposomes?

(OR)

8. a) Explain about the drug loading methods in resealed erythrocytes Systems?
   b) Write a short note on monoclonal antibodies?

9. a) Which type of materials is used in drug targeting into respiratory Systems? What is the importance of size of particles on drug absorption?
   b) Explain about the formulation of drugs to respiratory systems?

(OR)

10. a) What is the main character should the drug particles have target the brain and explain with examples? (4)
    b) Explain about the drug target to Brain. What the problems to target the drug into brain and how to overcome it explain with examples? (10)

MPPC 20212

M.Pharmacy Degree Examinations - September, 2015

II Semester - Pharmaceutics

Paper- II: Advanced Bio-Pharmaceutics

(Regulation 2012-13)

Time : 3 Hours Maximum Marks: 70

Answer all the questions. All questions carry the equal marks.

1. Define absorption. What are the various physiological factors affecting the drug absorption? Discuss in detail about any major four factors.

(OR)

2. What are the various routes of drug absorption? Explain about their bioavailability. Explain in detail about the various mechanisms of drug absorption across the cell membrane.

3. Define dissolution, disintegration. Discuss about the various physiological factors affecting the drug bioavailability.

(OR)

4. Explain about the physico-chemical factors affecting the drug dissolution. Explain the theories of drug dissolution.

5. What is the formulation factors affecting bio-availability of drug absorption in tablets?

(OR)

6. Discuss in detail about the effect various excipients on drug absorption.

7. Explain about the various compendial methods of drug dissolution. Discuss about the dissolution criteria and their limits. What are the methods to improve the dissolution rate?

(OR)

8. Explain about the IVIVC & what the various methods are. What are the conditions to be maintained in the dissolution? Write a short note on sink condition and how to achieve it?

9. Define bio availability. What is the use of these studies? What are the methods for assessment of bio availability?

(OR)

10. What are the bio-equivalence studies? Explain about the various designs and evaluation studies.

MPPC 20312

M.Pharmacy Degree Examinations - September, 2015

II Semester - Pharmaceutics

Paper- III: Advanced Pharmacokinetics

(Regulation 2012-13)

Time : 3 Hours | Maximum Marks: 70

Answer all the questions. All questions carry the equal marks.

1. Explain in detail about the 1-compartment-open-model for I.V. Bolus administration and discuss in detail about the all possible pharmacokinetic parameters.

(OR)

2. Explain in detail about the 1-compartment open model for extra vascular administration with respect to zero and first order kinetics. How to estimate K_a and K_E constants?

3. What are the tests to detect the non-linearity? Explain about the causes of Non-linearity.

(OR)

4. Explain about the Michaelis-Menton equation. How to estimate K_m and V_{max} from steady state concentration?

5. Write the classification of oral CDDS. Discuss about the influence of time dependent pharmaco-kinetics in the design of dosage form with suitable examples.

(OR)

6 a) Write a short note on chrono-pharmacokinetics (7)

b) What is the effect of various polymers on drug-delivery in site-specific drug release? (7)

7. Define metabolism. Classify the phase-I and phase-Il reactions. Explain any major 4 phase-I reactions with examples.

(OR)

8. What are the factors affecting the bio-transformation of drugs and explain in detail about them?

9. Explain about the mechanism of drug interactions. Discuss about the interactions affecting the absorption and distribution.

(OR)

10. What is the influence of alcohol and smoking on drug absorption? Discuss about the drug interactions affecting the metabolism and excretion.

MPPC 20412

M.Pharmacy Degree Examinations - September, 2015

II Semester - Pharmaceutics

Paper- IV: Advances in Drug Delivery Systems-II

(Regulation 2012-13)

Time : 3 Hours Maximum Marks: 70

Answer all the questions. All questions carry the equal marks.

1. Write about the physiology of cell membrane. Explain about the epithelial barriers of drug absorption?

(OR)

2. Explain about the transport across the cell membranes – efflux transporter layer.

3. (a) Explain about the ex-vivo and in-vivo gene therapy?
   (b) Write a short note on gene-expression system?

(OR)

4. (a) Explain about the gene delivery systems to liposomal systems.
   (b) Write a note on bio distribution.

5. Explain in detail about the human genome project and pharmaco-Genomics?

(OR)

6. Explain the factors influencing the drug disposition and effect on drug response.

7. Explain about the formulation and stability problems and evaluation of Recombinant proteins.

8. (a) Write a short note on Novel drug delivery systems of Insulin.
   (b) Write a short note on site specific proteins.

9. (a) Write the mechanism of uptake and transport of Antigens.
   (b) Write the mechanism of absorption enhancers.

10. (a) Explain about the peptide based vaccines.
    (b) Write a note on controlled released micro particles for vaccines.